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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,400	08/07/2001	Tony N. Frudakis	210121.419C12	7385

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER
ZEMAN, MARY K

ART UNIT	PAPER NUMBER
1631	10

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,400	FRUDAKIS ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2,5-7,12-14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8,11 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1, 3, 4, 8, 11-in-part (b) and 15, and SEQ ID NO: 302 and 303 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that A search of both sequences would not pose a burden upon the examiner as they are related. No arguments are provided with regard to the grouping of the claims or the independence of each group. Applicant's arguments regarding SEQ ID NO: 303 and 302 are persuasive and both sequences will be examined, but the remainder of the restriction is upheld.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 5-7, 9, 11-in-part (a) and (c)-(e), 12-14 and 16-17 *and all other sequences* are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

The amendment to the specification and the amendments to the claims filed 10/18/02 have each been entered.

Priority

Applicant is requested to update the status of the applications in the priority statement. For example, 08/991789 has issued as a patent, and so has 09/062789.

The earliest disclosure of the claimed sequences (SEQ ID NO: 302 and 303) is in application 09/289198, filed 4/9/1999. Therefore, all claims to those sequences are afforded 4/9/1999 as their effective filing date.

Information Disclosure Statement

The information disclosure statements filed 1/15/02 and 3/12/02 have been entered and considered. Initialed copies of the PTO-1449 forms are included with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 8, 11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. There are two parts to this rejection.

I) The specification fails to provide basis for the new limitations in claim 1 and claim 8 of "sequences consisting of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 303 from nucleotide 1888 to nucleotide 2731;" and "sequences that hybridize to a sequence provided by SEQ ID NO: 303 from nucleotide 1888 to nucleotide 2731 under moderately stringent conditions." The specification does not specifically point to these portions of the sequence as being particularly desirable nor does it name this particular subsequence as set forth in the amended claims. Applicant does not point out specific basis for these limitations and none is apparent. As such these limitations are NEW MATTER.

II) The specification discloses SEQ ID NO: 302 and 303 which corresponds to the splice variants of the gene coding for the Breast Cancer specific antigen B11Ag1 also referred to in the specification as B305D. Claims limited to the *particular disclosed sequences* related to this antigen, including SEQ ID NO: 203 and 303 would meet the written description provisions of 35 USC 112, first paragraph. However, claims 1 and 8 (and dependent claims thereon) are specifically directed to encompass sequences that hybridize to SEQ ID NO: 302 and 303, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 302 and 303, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing

a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the specifically disclosed sequences related to SEQ ID NO: 302 and 303, and related sequences which encode the disclosed antigen B11Ag1 (through codon degeneracy) but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 1 part (c)** recites the broad recitation "at least", and the claim also recites "consisting of" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 4, 8, 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Xu et al. (US 6,395,278 B1).

The claims are drawn to sequences comprising SEQ ID NO: 302 or 303, complementary sequences, sequences with at least 90% identity to SEQ ID NO: 302 or 303, sequences having at least 20 contiguous bases of SEQ ID NO: 302 or 303, sequences that hybridize to SEQ ID NO: 302 and 303, vectors, transformed host cells, and kits.

XU et al. (US Patent 6,395,278 B1) having a differing inventive entity, but the same assignee (Corixa Corporation) discloses SEQ ID NO: 374 which is 100% identical to SEQ ID NO: 302. XU also discloses SEQ ID NO: 375 which is 97% identical to SEQ ID NO: 302; SEQ ID NO: 369 which is 57% identical to SEQ ID NO: 302 and comprises at least 20 contiguous nucleotides of SEQ ID NO: 302 which would hybridize to SEQ ID NO: 302.

SEQ ID NO: 375 of XU is 100% identical to SEQ ID NO: 303. SEQ ID NO: 374 of XU is 95% identical to SEQ ID NO: 303. SEQ ID NO: 369 of XU is 56% identical to SEQ ID NO: 303 with at least 20 contiguous nucleotides of SEQ ID NO: 303 which would hybridize to SEQ ID NO: 303.

XU et al. contemplate vectors, transformed host cells, kits, methods of producing polypeptides, and methods of diagnosis of prostate cancer.

Claims 1, 3, 4, 8, 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Xu et al. (US 6,329,505 B1).

XU et al. (US Patent 6,329,505 B1) having a differing inventive entity, but the same assignee (Corixa Corporation) discloses SEQ ID NO: 374 which is 100% identical to SEQ ID NO: 302. XU also discloses SEQ ID NO: 375 which is 97% identical to SEQ ID NO: 302; SEQ ID NO: 369 which is 57% identical to SEQ ID NO: 302 and comprises at least 20 contiguous nucleotides of SEQ ID NO: 302 which would hybridize to SEQ ID NO: 302.

SEQ ID NO: 375 of XU is 100% identical to SEQ ID NO: 303. SEQ ID NO: 374 of XU is 95% identical to SEQ ID NO: 303. SEQ ID NO: 369 of XU is 56% identical to SEQ ID NO: 303 with at least 20 contiguous nucleotides of SEQ ID NO: 303 which would hybridize to SEQ ID NO: 303.

XU et al. contemplate vectors, transformed host cells, kits, methods of producing polypeptides, and methods of diagnosis of prostate cancer.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Frudakis et al. (6,344,550) CLAIMS SEQ ID NO : 295, which has identity to SEQ ID NO : 302 and 303, but this identity falls outside the specifically recited area in claims 1 and 11. If Applicant amends the claims to remove the limitation regarding from where the 20 contiguous nucleotides are to be chosen, *this art may be applied and made final and double patenting issues may apply.*

Frudakis et al. (WO 98/45328) discloses the DNA molecule encoding peptide #188, which has significant identity to SEQ ID NO : 302 and 303, but this identity falls outside the specifically recited area in claims 1 and 11. If Applicant amends the claims to remove the limitation regarding from where the 20 contiguous nucleotides are to be chosen, *this art may be applied and made final.*

Genbank Accession Number AA533501, 21 August 1997, discloses a DNA molecule which has significant identity to SEQ ID NO : 302 and 303, but this identity falls outside the specifically recited area in claims 1 and 11. If Applicant amends the claims to remove the limitation regarding from where the 20 contiguous nucleotides are to be chosen, *this art may be applied and made final.*

Genbank Accession Number AQ063365, 31 July 1998, discloses a DNA molecule which has significant identity to SEQ ID NO : 302 and 303, but this identity falls outside the specifically recited area in claims 1 and 11. If Applicant amends the claims to remove the limitation regarding from where the 20 contiguous nucleotides are to be chosen, *this art may be applied and made final.*

Genbank Accession Number AQ124119, 22 September 1998, discloses a DNA molecule which has significant identity to SEQ ID NO : 302 and 303, but this identity falls outside the specifically recited area in claims 1 and 11. If Applicant amends the claims to remove the limitation regarding from where the 20 contiguous nucleotides are to be chosen, *this art may be applied and made final.*

Genbank Accession Number AQ204617, 17 September 1998, discloses a DNA molecule which has significant identity to SEQ ID NO : 302 and 303, but this identity falls outside the specifically recited area in claims 1 and 11. If Applicant amends the claims to remove the limitation regarding from where the 20 contiguous nucleotides are to be chosen, *this art may be applied and made final.*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.
mkz
11/13/02

MARY K. ZEMAN
PRIMARY EXAMINER
AU 1631